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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Mark R. Prausnitz, Mark G. Allen, and Inder-Jeet Gujral

Serial No.: 09/453,109

Art Unit:

Filed: December 2, 1999

Examiner: Not Yet Assigned

For: *MICRONEEDLE DEVICE FOR EXTRACTION AND SENSING OF BODILY FLUIDS*

Assistant Commissioner for Patents  
Washington, D.C. 20231

**INFORMATION DISCLOSURE STATEMENT**

Sir:

Pursuant to 37 C.F.R. §1.56 and 37 C.F.R. §1.97, Applicants submit an Information Disclosure Statement, including seven (7) pages of Form PTO-1449 and a copy of each document cited therein.

This Information Disclosure Statement is being filed under 37 C.F.R. § 1.97(b) prior to a first Office Action on the merits. It therefore is believed that no fee is required with this submission. However, should a fee be required, the Commissioner is hereby authorized to charge any required fees to Deposit Account No. 01-2507. A duplicate of this transmittal is enclosed to facilitate the process.

**U.S. Patents**

<u>Number</u>	<u>Issue Date</u>	<u>Patentee</u>	<u>Class/Subclass</u>
Re. 25,637	09-08-1964	Kravitz, et al.	128/253
2,893,392	07-07-1959	Wagner, et al.	128/253
3,034,507	05-15-1962	McConnell, et al.	128/253
3,086,530	04-23-1963	Groom	128/329
3,123,212	03-03-1964	Taylor, et al.	206/63.4
3,136,314	06-09-1964	Kravitz	128/253
3,221,739	12-07-1965	Rosenthal	128/253
3,221,740	12-07-1965	Rosenthal	128/253

U.S.S.N.: 09/453,109  
 Filed: December 2, 1999  
 INFORMATION DISCLOSURE STATEMENT

3,556,080	01-19-1971	Hein	128/2
3,596,660	08-03-1971	Melone	128/253
3,675,766	07-11-1972	Rosenthal	206/63.4
3,918,449	11-11-1975	Pistor	128/218 R
3,964,482	06-22-1976	Gerstel, et al.	128/260
4,109,655	08-29-1978	Chacornac	128/253
4,159,659	07-03-1979	Nightingale	81/9.22
4,222,392	09-16-1980	Brennan	128/743
4,320,758	03-23-1982	Eckenhoff, et al.	128/260
4,771,660	09-20-1988	Yacowitz	81/9.22
4,798,582	01-17-1989	Sarath, et al.	604/47
4,921,475	05-01-1990	Sibalis	604/20
4,969,468	11-13-1990	Byers, et al.	128/642
5,035,711	07-30-1991	Aoki, et al.	623/11
5,054,339	10-08-1991	Yacowitz	81/9.22
5,138,220	08-11-1992	Kirkpatrick	313/309
5,250,023	10-05-1993	Lee, et al.	604/20
5,279,544	01-18-1994	Gross, et al.	604/140
5,279,552	01-18-1994	Magnet	604/47
5,335,670	08-09-1994	Fishman	128/743
5,364,374	11-15-1994	Morrison, et al.	604/272
5,383,512	01-24-1995	Jarvis	164/46
5,401,242	03-28-1995	Yacowitz	604/48
5,457,041	10-10-1995	Ginaven, et al.	435/172.1
5,527,288	06-18-1996	Gross, et al.	604/140
5,582,184	12-10-1996	Erickson, et al.	128/763
5,591,139	01-07-1997	Lin, et al.	604/264
5,605,662	02-25-1997	Heller, et al.	422/68.1
5,611,806	03-18-1997	Jang	606/167
5,611,809	03-18-1997	Marshall, et al.	606/181
5,618,295	04-08-1997	Min	606/171
5,632,957	05-27-1997	Heller, et al.	422/68.1
5,658,515	08-19-1997	Lee, et al.	264/219
5,697,901	12-16-1997	Eriksson	604/46
5,801,057	09-01-1998	Smart, et al.	436/68
5,843,114	12-01-1998	Jang	606/186
5,848,991	12-15-1998	Gross, et al.	604/140
5,852,495	12-22-1998	Parce	356/344
5,858,188	01-12-1999	Soane, et al.	204/454
5,865,786	02-02-1999	Sibalis, et al.	604/20
5,876,675	03-02-1999	Kennedy	422/99
5,879,326	03-09-1999	Godshall, et al.	604/51
5,883,211	03-16-1999	Sassi, et al.	526/307.2

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### Foreign Patent Documents

<u>Number</u>	<u>Publication Date</u>	<u>Patentee</u>	<u>Country</u>
0 652 600 A1	05-10-1995	Matsushita Electric Industrial Co., Ltd.	EP
7-132119 A ✓	05-23-1995	Nikon Corp.	JP
7-196314 A	08-01-1995	Maruo Calcium KK	JP
WO 93/17754 A1	09-16-1993	Elan Medical Technologies Ltd.	PCT
WO 96/37256 A1	11-28-1996	Silicon Microdevices, Inc.	PCT
WO 96/40365 A1	12-19-1996	Alza Corporation	PCT
WO 96/41236 A1	12-19-1996	The Regents of the University of California	PCT
WO 97/07734 A1 ✓	03-06-1997	SpectRx, Inc.	PCT
WO 98/00193 A1 ✓	01-08-1998	Altea Technologies, Inc.	PCT
WO 98/28037 A1	07-02-1998	Alza Corporation	PCT

### Publications

"Single-crystal whiskers," *Biophotonics Int'l* p. 64 (Nov./Dec. 1996).

"101 Uses for Tiny Tubules," *Science* 247 (March, 1990).

AMSDEN & GOOSEN, "Transdermal Delivery of Peptide and Protein Drugs: an Overview," *AIChE Journal* 41(8):1972-97 (1995).

BRONAUGH & MAIBACH, Percutaneous Absorption, Mechanisms--Methodology--Drug Delivery, (Marcel Dekker:New York, 1989).

BRUMLIK & MARTIN, "Template Synthesis of Metal Microtubules," *J. Am. Chem. Soc.* 113:3174-75 (1991).

DESPONT, et al., "High-Aspect-Ratio, Ultrathick, Negative-Tone Near-UV Photoresist for MEMS Applications," *Proc. of IEEE 10<sup>th</sup> Annual International Workshop on MEMS*, Nagoya, Japan, pp. 518-22 (Jan. 26-30, 1997).

EDELL, et al., "Factors Influencing the Biocompatibility of Insertable Silicon Microshafts in Cerebral Cortex," *IEEE Transactions on Biomedical Engineering* 39(6):635-43 (1992).

FRAZIER & ALLEN, "Metallic Microstructures Fabricated Using Photosensitive Polyimide Electroplating Molds," *Journal of Microelectromechanical Systems* 2:87-97 (1993).

FRAZIER, et al., "Two dimensional metallic microelectrode arrays for extracellular stimulation and recording of neurons", *IEEE Proceedings of the Micro Electro Mechanical Systems Conference*, pp. 195-200 (1993).

HADGRAFT & GUY, eds., Transdermal Drug Delivery: Developmental Issues and Research Initiatives, (Marcel Dekker:New York, 1989).

HAGA, et al., "Transdermal iontophoretic delivery of insulin using a photoetched microdevice," *J. Controlled Release* 43:139-49 (1997).

HASHMI, et al., "Genetic Transformation of Nematodes Using Arrays of Micromechanical Piercing Structures," *BioTechniques* 19(5):766-70 (1995).

HENRY, et al., "Microfabricated microneedles: A novel approach to transdermal drug delivery" *J. Pharm. Sci.* 87:922-25 (1998).

HENRY, et al., "Micromachined Needles for the Transdermal Delivery of Drugs," *Micro Electro Mechanical Systems*, Heidelberg, Germany, pp. 494-98 (Jan. 26-29, 1998).

HOFFERT, "Transcutaneous methods get under the skin," *The Scientist* 12 (1998).

JAEGER, Introduction to Microelectronic Fabrication (Addison-Wesley Publishing Co.:Reading MA 1988).

JANSEN, et al., "The Black Silicon Method IV: The Fabrication of Three-Dimensional Structures in Silicon with High Aspect Ratios for Scanning Probe Microscopy and Other Applications," *IEEE Proceedings of Micro Electro Mechanical Systems Conference*, pp. 88-93 (1995).

LAERMER, et al., "Bosch Deep Silicon Etching: Improving Uniformity and Etch Rate for Advanced MEMS Applications," *Micro Electro Mechanical Systems*, pp. 211-16, Orlando, FL, USA, (Jan. 17-21, 1999).

LANGER, "Drug Delivery and Targeting," *Nature* 392:5-10 (1998).

LEHMANN, "Porous Silicon--A New Material for MEMS", *IEEE Proceedings of the Micro Electro Mechanical Systems Conference*, pp. 1-6 (1996).

LIN, et al., "Silicon Processed Microneedles," *The 7<sup>th</sup> International Conference on Solid-State Sensors and Actuators* 237-40 (1993).

MARTIN, et al., "Template Synthesis of Organic Microtubules," *J. Am. Chem. Soc.* 112:8976-77 (1990).

NAJAFI & HETKE, "Strength Characterization of Silicon Microprobes in Neurophysiological Tissues," *IEEE Transcriptions on Biomedical Engineering* 37(5):474-81 (1990).

PRAUSNITZ, "Reversible Skin Permeabilization for Transdermal Delivery of Macromolecules," *Critical Reviews in Therapeutic Drug Carrier Systems* 14(4):455-83 (1997).

*Proceedings of the IEEE Micro Electro Mechanical Systems Conference 1987-1998*; Rai-Choudhury, ed., Handbook of Microlithography, Micromachining & Microfabrication (SPIE Optical Engineering Press: Bellingham, WA 1997).

QUAN, "Plasma etch yields microneedle arrays," *Electronic Engineering Times* 63:63-64 (1998).

REISS, "Glucose- and Blood-Monitoring Systems Vie for Top Spot," *Biophotonics Int'l*, pp. 43-45 (1997).

RUNYAN & BEAN, Semiconductor Integrated Circuit Processing Technology, Addison-Wesley Publishing Co.: Reading, MA, 1990.

SCHIFT, et al., "Fabrication of replicated high precision insert elements for micro-optical bench arrangements" *Proc. SPIE - International Soc. Optical Engineer* 3513:122-34 (1998).

TALBOT & PISANO, "Polymolding: Two Wafer Polysilicon Micromolding of Closed-Flow Passages for Microneedles and Microfluidic Devices," *Solid-State Sensor and Actuator Workshop Hilton Head Island, South Carolina, June 8-11* 266-68 (1988).

TRIMMER, et al., "Injection of DNA into Plant and Animal Tissues with Micromechanical Piercing Structures," *IEEE Proceedings of Micro Electro Mechanical Systems Conference*, pp. 111-15 (1995).

WEBER, et al., "Micromolding - a powerful tool for the large scale production of precise microstructures," *Proc. SPIE - International Soc. Optical Engineer* 2879:156-67 (1996).

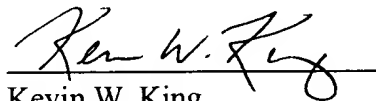
ZUSKA, "Microtechnology Opens Doors to the Universe of Small Space," *Medical Device and Diagnostic Industry*, p. 131 (1997).

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Filed: December 2, 1999  
INFORMATION DISCLOSURE STATEMENT

### Remarks

This statement should not be interpreted as a representation that an exhaustive search has been conducted or that no better art exists. Moreover, Applicants invite the Examiner to make an independent evaluation of the cited art to determine its relevance to the subject matter of the present application. Applicants are of the opinion that their claims patentably distinguish over the art referred to herein, either alone or in combination.

Respectfully submitted,



Kevin W. King  
Reg. No. 42,737

Dated: January 19, 2000

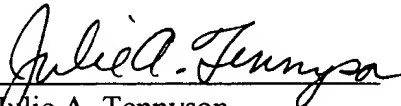
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Filed: December 2, 1999  
INFORMATION DISCLOSURE STATEMENT

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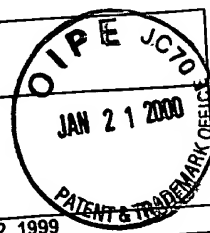
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# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Complete if Known

Application Number	09/453,109
Filing Date	December 2, 1999
First Named Inventor	Mark R. Prausnitz
Group Art Unit	
Examiner Name	
Attorney Docket Number	GTRC 2139



Sheet 1 of 7

## U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	US Patent Document		Name of Patentee or Applicant of Cited Document	Date of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code <sup>2</sup> (if known)			
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		4,921,475		Sibalis	05-01-1990	
		4,969,468		Byers, et al.	11-13-1990	
		5,035,711		Aoki, et al.	07-30-1991	
		5,054,339		Yacowitz	10-08-1991	
		5,138,220		Kirkpatrick	08-11-1992	
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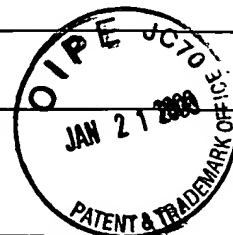
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Sheet	2	of	7



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		5,279,552		Magnet	01-18-1994	
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		5,364,374		Morrison, et al.	11-15-1994	
		5,383,512		Jarvis	01-24-1995	
		5,401,242		Yacowitz	03-28-1995	
		5,457,041		Ginaven, et al.	10-10-1995	
		5,527,288		Gross, et al.	06-18-1996	
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		5,605,662		Heller, et al.	02-25-1997	
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		5,611,809		Marshall, et al.	03-18-1997	
		5,618,295		Min	04-08-1997	
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		5,658,515		Lee, et al.	08-19-1997	
		5,697,901		Eriksson	12-16-1997	
		5,801,057		Smart, et al.	09-01-1998	
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		5,848,991		Gross, et al.	12-15-1998	
		5,852,495		Parce	12-22-1998	
		5,858,188		Soane, et al.	01-12-1999	
		5,865,786		Sibalis, et al.	02-02-1999	
		5,876,675		Kennedy	03-02-1999	
		5,879,326		Godshall, et al.	03-09-1999	
		5,883,211		Sassi, et al.	03-16-1999	

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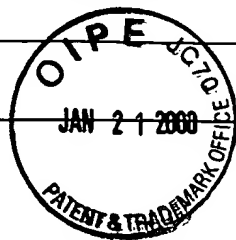
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OTHER ART – NON PATENT LITERATURE DOCUMENTS			
Examiner's Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>4</sup>
		"Single-crystal whiskers," <i>Biophotonics Int'l</i> p. 64 (Nov./Dec. 1996).	
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		AMSDEN & GOOSEN, "Transdermal Delivery of Peptide and Protein Drugs: an Overview," <i>AIChE Journal</i> 41(8):1972-1997 (1995).	
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		BRUMLIK & MARTIN, "Template Synthesis of Metal Microtubules," <i>J. Am. Chem. Soc.</i> 113:3174-3175 (1991).	
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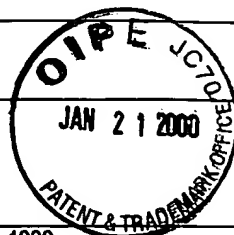
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		HAGA, et al., "Transdermal iontophoretic delivery of insulin using a photoetched microdevice," <i>J. Controlled Release</i> 43:139-49 (1997).	
		HASHMI, et al., "Genetic Transformation of Nematodes Using Arrays of Micromechanical Piercing Structures," <i>BioTechniques</i> 19(5):766-70 (1995).	
		HENRY, et al., "Microfabricated microneedles: A novel method to increase transdermal drug delivery" <i>J. Pharm. Sci.</i> 87:922-25 (1998).	
		HENRY, et al., "Micromachined Needles for the Transdermal Delivery of Drugs," <i>Micro Electro Mechanical Systems</i> , Heidelberg, Germany, pp. 494-98 (Jan. 26-29, 1998).	
		HOFFERT, "Transcutaneous methods get under the skin," <i>The Scientist</i> 12 (1998).	
		JAEGER, <i>Introduction to Microelectronic Fabrication</i> (Addison-Wesley Publishing Co., Reading MA 1988).	
		JANSEN, et al., "The Black Silicon Method IV: The Fabrication of Three-Dimensional Structures in Silicon with High Aspect Ratios for Scanning Probe Microscopy and Other Applications," <i>IEEE Proceedings of Micro Electro Mechanical Systems Conference</i> , pp. 88-93 (1995).	
		LAERMER, et al., "Bosch Deep Silicon Etching: Improving Uniformity and Etch Rate for Advanced MEMS Applications," <i>Micro Electro Mechanical Systems</i> , Orlando, FL, USA, (Jan. 17-21, 1999);	
		LANGER, "Drug Delivery and Targeting," <i>Nature</i> 392:5-10 (1998).	
		LEHMANN, "Porous Silicon--A New Material for MEMS", <i>IEEE Proceedings of the Micro Electro Mechanical Systems Conference</i> , pp. 1-6 (1996).	

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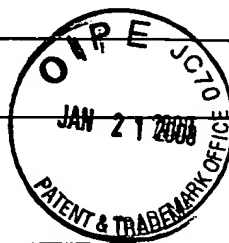


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		Filing Date	December 2, 1999
		First Named Inventor	Mark R. Prausnitz
		Group Art Unit	
		Examiner Name	
Sheet 6 of 7	Attorney Docket Number	GTRC 2139	



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		LIN, et al., "Silicon Processed Microneedles," <i>The 7<sup>th</sup> International Conference on Solid-State Sensors and Actuators</i> 237-240 (1993).	
		MARTIN, et al., "Template Synthesis of Organic Microtubules," <i>J. Am. Chem. Soc.</i> 112:8976-8977 (1990).	
		NAJAFI, et al., "Strength Characterization of Silicon Microprobes in Neurophysiological Tissues," <i>IEEE Transactions on Biomedical Engineering</i> 37(5): 474-481 (1990).	
		PRAUSNITZ, "Reversible Skin Permeabilization for Transdermal Delivery of Macromolecules," <i>Critical Reviews in Therapeutic Drug Carrier Systems</i> 37(5): 474-481 (1990).	
		<i>Proceedings of the IEEE Micro Electro Mechanical Systems Conference 1987-1998</i> ; Rai-Choudhury, ed., <i>Handbook of Microlithography, Micromachining &amp; Microfabrication</i> (SPIE Optical Engineering Press, Bellingham, WA 1997).	
		QUAN, "Plasma etch yields microneedle arrays," <i>Electronic Engineering Times</i> 63:63-64 (1998).	
		REISS, "Glucose- and Blood-Monitoring Systems Vie for Top Spot," <i>Biophotonics Int'l</i> , pp. 43-45 (1997).	
		RUNYAN, et al., <i>Semiconductor Integrated Circuit Processing Technology</i> , Addison-Wesley Publishing Co.:Reading, MA, 1990.	
		SCHIFT, et al., "Fabrication of replicated high precision insert elements for micro-optical bench arrangements" <i>Proc. SPIE - International Soc. Optical Engineer</i> 3513:122-134 (1998).	
		TALBOT & PISANO, "Polymolding: Two Wafer Polysilicon Micromolding of Closed-Flow Passages for Microneedles and Microfluidic Devices," <i>Solid-State Sensor and Actuator Workshop Hilton Head Island, South Carolina, June 8-11</i> 266-268 (1988).	

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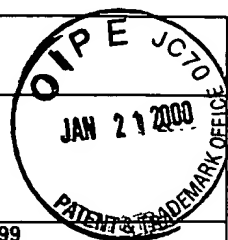


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		TRIMMER, et al., "Injection of DNA into Plant and Animal Tissues with Micromechanical Piercing Structures," <i>IEEE Proceedings of Micro Electro Mechanical Systems Conference</i> , pp. 111-15 (1995).	
		WEBER, et al., "Micromolding - a powerful tool for the large scale production of precise microstructures," <i>Proc. SPIE - International Soc. Optical Engineer</i> 2879:156-167 (1996).	
		ZUSKA, "Microtechnology Opens Doors to the Universe of Small Space," <i>Medical Device and Diagnostic Industry</i> , p. 131 (1997).	

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